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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,837	SWEENEY ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-32 and 34-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-32,34 and 40-48* is/are rejected.

7)☒ Claim(s) *39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-6, 16 and 17 as anticipated under 35 U.S.C. §102(b) by Siegel'841 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the disclosed sizing of 5cm by 2cm in column 12, lines 65-67 of Siegel'841 is considered to be of sufficient size and shape to be capable of being implanted within a myocardium of a subject, e.g. in one of the ventricular chambers.

2. Applicant's arguments, see paragraph 1 of page 11, filed 17 December 2007, with respect to the rejection(s) of claim(s) 1-7, 11-17, 19-29, 37 and 43 under 35 U.S.C. §102(e) as anticipated by Lew'822 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the previously applied art in view of a newly found prior art reference.

3. Applicant's arguments, see pages 12-13, filed 17 December 2007, with respect to the rejection of claims 1-33, 36-38 and 40-46 under 35 U.S.C. §102(e) as anticipated by Slepiain'849 have been fully considered and are persuasive. The Slepian'849 rejection of claims 1-33, 36-38 and 40-46 has been withdrawn.

4. Applicant's arguments, see page 15, paragraph 1, filed 17 December 2007, with respect to the rejection of claims 1-8, 10-12, 16-30, 33, 37, 38, 40, 41, 43 and 46 under 35 U.S.C. §102(b) as anticipated by Unger'923 have been fully considered and are

persuasive. The Unger'923 rejection of claims 1-8, 10-12, 16-30, 33, 37, 38, 40, 41, 43 and 46 has been withdrawn.

5. Applicant's arguments, see pages 16 and 17, filed 17 December 2007, with respect to the rejection of claims 18, 19, 34, 40, 42, 43, 47 and 48 under 35 U.S.C. §102(b) as anticipated by Sutton'186 have been fully considered and are persuasive. The Sutton'186 rejection of claims 18, 19, 34, 40, 42, 43, 47 and 48 has been withdrawn.

5. Applicant's arguments, see page 18 through page 19, paragraph 2, filed 17 December 2007, with respect to the rejection(s) of claim(s) 1—17, 19-33, 35, 36, 38 and 43-46 under 35 U.S.C. §103(a) as unpatentable over Altman'630 in view of Lew'822 and further in view of Siegel'841 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the previously applied art further in view of a newly found prior art reference.

6. Applicant's arguments, see page 19 paragraph 3, filed 17 December 2007, with respect to the rejection of claims 34, 47 and 48 under 35 U.S.C. §103(a) as unpatentable over Slepian'849 or Unger'923 in view of Sutton'186 have been fully considered and are persuasive. The §103(a) rejections of claims 34, 47, and 48 relying on Slepian'849 and Unger'923 have been withdrawn.

7. Applicant's arguments with respect to claims 34, 47 and 48 being rejected under 35 U.S.C. §103(a) as unpatentable over Lew'822 in view of Sutton'186 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel (U.S. Patent No. 5,062,841, hereinafter Siegel'841) in view of Hemmingsson (US 6,421,565, hereinafter Hemmingsson'565) or in view of Nappholz et al. (US 5,188,106, hereinafter Nappholz'106).

Regarding claims 1, 2, 16 and 17, Siegel'841 teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel'841 also teaches that the swellable member swells in response to an increase in blood glucose level (col. 3 lines 51-56) and that the swellable member is disclosed as, or inherently capable of, implantation in contact with the tissue since it is disclosed as being in a housing open such that it can contact body fluids (abstract). In regards to claims 1 and 2, Examiner takes the position that the hydrogel membrane as taught by Siegel'841 has at least one physical property (swelling) that changes in response to a physiological condition (an increase in blood glucose level). Further, Examiner takes the position that change in size due to swelling, is inherently detectable by use of acoustic energy. Factual support for this assertion can be found in Hood (US 5,324,297) and Kaplan (US 6,770,032). Since Hood'297

discloses that ultrasound can be delivered at an energy so as to cut through a PMMA housing, it is clear that ultrasound could also be provided at a lower energy so as to leave the housing in tact but nonetheless be sufficient of energy to provide imaging resolution to monitor the change of size of the swellable member of Siegel'841. Kaplan'032 teaches of using ultrasound imaging to project through the front surface of a housing and sensing the diminished by still present signal reflected from the back portion of the housing. Since the ultrasound is able to detect the signal from the rear-facing portion of this housing, it is supported that it could also distinguish the signal created by a material placed there between, albeit a small signal, such as from the swellable member of Siegel. It is further noted that the disclosed size of 5cm by 2cm (column 12, lines 65-67) is considered to be a size capable of being implanted within a myocardium, for example within one of the ventricular cavities.

Further regarding claim 1, Siegel'841 is considered to disclose the invention substantially as claimed, but does not expressly disclose that the transducer is implantable. In the same field of endeavor, Hemmingsson'565 teaches an implantable ultrasound probe placed in the right ventricle of the heart in order to monitor cardiac performance (claim 17). Similarly, in the same field of endeavor, Nappholz'106 teaches implanting an ultrasound transducer in the cardiac structures in order to provide the best technique for measuring cardiac output and stroke volume to give the best index of aortic and systemic blood flow (column 5, lines 58-68; column 12, liens 25-39; column 27, lines 4-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Siegel'841 with the

implantable ultrasound transducer of either Hemmingsson'565 or Nappholz'106 to provide the best technique for monitoring cardiac performance and movement of the cardiac structures through ultrasound imaging.

In regards to claims 3-6, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size.

10. Claims 1-7, 11-17, 19-29, 37, 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lew et al. (US 2003/0100822, hereinafter Lew'822) in view of Hemmingsson'565 or in view of Nappholz'106.

Lew'822 is considered to clearly disclose the invention as claimed substantially in the title, abstract, and Figures 1, 2, 7A, 10A, 11-13, 15-17 and their supporting paragraphs. It is noted that Lew'822 discloses that the physiological sensor is chronic in nature (paragraphs [7], [50], [62], [74]). Lew'822 does not expressly disclose that the ultrasound transducer is implantable. In the same field of endeavor, Hemmingsson'565 teaches an implantable ultrasound probe placed in the right ventricle of the heart in order to monitor cardiac performance (claim 17). Similarly, in the same field of endeavor, Nappholz'106 teaches implanting an ultrasound transducer in the cardiac structures in order to provide the best technique for measuring cardiac output and stroke volume to give the best index of aortic and systemic blood flow (column 5, lines 58-68; column 12, liens 25-39; column 27, lines 4-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Lew'822 with the implantable ultrasound transducer of either

Hemmingsson'565 or Nappholz'106 to provide the best technique for monitoring cardiac performance and movement of the cardiac structures through ultrasound imaging.

Regarding claims 7 and 32, Lew'822 discloses the invention substantially as claimed, but does not explicitly disclose that the body is sized to be less than or equal to 50 micrometers in diameter. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a diameter of 50 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) of a result effective variable involves only routine skill in the art.

11. Claims 1-7, 9, 11-17, 19-29, 31, 32, 35, 36, 38, and 43-46 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630, hereinafter Altman'630) in view of Lew'822, and further in view of Siegel'841 as applied above; still further in view of Hemmingsson'565 or Nappholz'106.

Regarding claims 1, 19 and 43, Altman'630 discloses an implantable cardiac drug delivery system for delivery agents to be introduced within the myocardium of a subject (col. 9 lines 32-35), comprising a delivery patch or patches that may consist of a hydrogel (col. 12 lines 11-13), a catheter (col. 7 lines 56-61), and the use of an acoustic transmitter (col. 20 lines 39-43). Altman'630 does not specifically teach that hydrogels are commonly known in the art to be pH and/or ion sensitive, nor does Altman'630 teach that hydrogels are commonly known in the art to swell in response to a physiological condition.

Lew'822 teaches that hydrogels, including pH sensitive hydrogels, are well known in the art for being used as chronic protective biocompatible coating for implantable devices, and are further defined as polymeric materials that swell in water and other fluids (paragraphs 7 and 9).

Siegel'841 teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swellable member swells in response to an increase in blood glucose level (col. 3 lines 51-56).

Examiner takes the position that hydrogel membrane that makes of the patch as taught by Altman'630 would be inherently capable of having at least one physical property change (swelling in size) in response to a physiological condition, such as an increase in blood glucose level since it is known that hydrogels have the characteristic, as taught by Siegel'841 (col. 3 lines 51-56).

Further regarding claims 1, 19 and 43, Altman'630 is considered to disclose the invention substantially as claimed, but does not expressly disclose an implantable ultrasound transducer. In the same field of endeavor, Hemmingsson'565 teaches an implantable ultrasound probe placed in the right ventricle of the heart in order to monitor cardiac performance (claim 17). Similarly, in the same field of endeavor, Nappholz'106 teaches implanting an ultrasound transducer in the cardiac structures in order to provide the best technique for measuring cardiac output and stroke volume to give the best index of aortic and systemic blood flow (column 5, lines 58-68; column 12, liens 25-39;

column 27, lines 4-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Altman'630 with the implantable ultrasound transducer of either Hemmingsson'565 or Nappholz'106 to provide the best technique for monitoring cardiac performance and movement of the cardiac structures through ultrasound imaging.

Further in regards to claim 19, the additional limitations of the claim are clearly anticipated by Lew'822 in the Abstract, as well as Figures 2, 11, 16 and 17.

In regards to claims 3-6 and 22-29, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size. In the alternative, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Altman'630 include hydrogels that are capable of swelling as taught by both Lew et al. and Siegel'841, since the hydrogels as taught by both Lew'822 and Siegel'841 are well known in the art for being biocompatible membranes.

Regarding claims 7 and 32, Altman'630 discloses the invention substantially as claimed, but does not explicitly disclose that the body is sized to be less than or equal to 50 micrometers in diameter. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a diameter of 50 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) of a result effective variable involves only routine skill in the art.

In regards to 12-15, Examiner takes the position that Altman'630 inherently teaches of the use of a display, user interface and an external programmer, since the ultrasound transducer is being used in connection with ultrasound imaging (col. 20 lines 39-42). Examiner also takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system to include use of a computer network in connection with the user interface, since it is well known in the art to use a network for enhanced feedback and communication of detected results.

Regarding claim 38, Altman'630 discloses a body sized and shaped to be introduced within a vein or artery (column 9, lines 55-66; column 11, lines 24-39).

Regarding claim 43, an implantable medical device including a state that is altered using a change in the physical property is disclosed both by Siegel'841 (ABSTRACT) and by Lew'822 (ABSTRACT, where the hydrogel is considered the IMD which alters its size in response to the change in analyte concentration adjacent to it).

Regarding claims 36, 44 and 45, Altman'630 discloses an implantable medical device including an intravascular lead with an acoustic transducer (column 27, lines 13-44).

Regarding claim 46, Siegel'841 discloses modifying a therapy using the detected change in the physiological condition (ABSTRACT).

12. Claims 8, 18, 30 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lew'822 in view of Hemmingsson'565 or in view of Nappholz'106 as applied to claims 1 and 19 above, and further in view of Widder et al. (US 4,345,588, hereinafter Widder'588).

Lew'822 in view of Hemmingsson'565 or in view of Nappholz'106 is considered to disclose the invention substantially as claimed as described in paragraph 11 above, but does not expressly disclose that the body comprise a plurality of chronically placed biocompatible microspheres. In the same problem solving area, Widder'588 teaches using a magnetic field, i.e. an imaging field, to permanently immobilize microspheres in a target capillary bed in order to delivery a contained therapeutic agent while allowing normal blood flow to continue (column 3, lines 45-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Lew'822 with the permanent microspheres as taught by Widder'588 to provide Lew'822 with the same advantages of immobilizing the microspheres in the target capillary bed while allowing normal blood flow to continue.

13. Claims 8, 18, 30 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman'630 in view of Lew'822, further in view of Siegel'841, still further in view of Hemmingsson'565 or Nappholz'106 as applied to claims 1 and 19 above, and further in view of Widder'588.

Altman'630 is considered to disclose the invention substantially as claimed as described in paragraph 12 above, but does not expressly disclose that the body comprise a plurality of chronically placed biocompatible microspheres. In the same problem solving area, Widder'588 teaches using a magnetic field, i.e. an imaging field, to permanently immobilize microspheres in a target capillary bed in order to delivery a contained therapeutic agent while allowing normal blood flow to continue (column 3, lines 45-61). Therefore, it would have been obvious to one of ordinary skill in the art at

the time of the invention to modify the system of Altman'630 with the permanent microspheres as taught by Widder'588 to provide Altman'630 with the same advantages of immobilizing the microspheres in the target capillary bed while allowing normal blood flow to continue.

14. Claims 34, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lew'822 in view of Hemmingsson'565 or in view of Nappholz'106 as applied to claims 19 and 43 above, and further in view of Sutton et al (US 6,348,186, hereinafter Sutton'186).

Lew'822 discloses the invention substantially as claimed in claims 19 and 43 including swellable ultrasound contrasting agents that have a physical characteristic change detected by ultrasound, but do not expressly disclose that that which is detected thereby is ischemia. In the same field of endeavor, Sutton'186 discloses that ultrasound contrast agents can serve to enhance echoes from arterial blood for the detection of ischemia (column 11, lines 55-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lew'822 to detect ischemia, since Sutton'186 teaches that ultrasound agents such as those disclosed in each of those references can be used to detect ischemia when placed in arterial blood.

Allowable Subject Matter

15. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

12 March 2008

/George Manuel/
Primary Examiner